Express Mail No. EV 361 327 755 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Parkin et al.	Confirmation No.:	4526
Serial No.:	10/612,600	Art Unit:	1648
Filed:	July 1, 2003	Examiner:	Jeffrey S. Parkin
For:	Methods and Compositions for Determining the Susceptibility of a Pathogenic Virus to Protease Inhibitors	Attorney Docket No.:	11068-015-999

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This paper responds to the Restriction Requirement mailed March 31, 2006 in connection with the above identified patent application.

Filed herewith is a Petition for Extension of Time for 3 months' Extension of Time for response from April 30, 2006 to and including July 31, 2006.

In the Restriction Requirement, the Patent Office restricted the claims of the instant application into eight groups: Groups I-VI, drawn to methods for determining increased protease inhibitor hypersusceptibility, Group VII, drawn to an isolated oligonucleotide comprising a PR mutation, and Group VIII, drawn to a method for determining decreased protease inhibitor hypersusceptibility.

In response to the Restriction Requirement, Applicants hereby elect, with traverse, to pursue the claims of Group **I**, claims 1-4, 6, 7, 18, and 19, drawn to a method for determining amprenavir susceptibility. Applicants traverse on the grounds that under the controlling legal standard, restriction under 35 U.S.C. § 121 of the subject matter of a single claim is improper and impermissible. As such, Applicants respectfully request that the subject matter recited by the claims of Groups I-VI should be rejoined and examined on the merits.

The Court of Customs and Patent Appeals extensively discussed and decided the issue of restriction within a single claim in *In re Weber, Soder, and Boksay*, 198 U.S.P.Q. 328 (C. C. P. A., 1978) ("*Weber*"). In that case, the Court stated that

> [a]s a general proposition, an applicant has the right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant to eventually have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim...
>
> It is apparent that § 121 provides the Commissioner with the authority to promulgate rules designed to *restrict* an *application* to one of several claimed inventions when those inventions are found to be "independent and distinct." It does not, however, provide a basis for an examiner acting under the authority of the Commissioner to *reject* a particular *claim* on the same basis.

Id. at 331-332 (emphasis in the original). The same court also held that refusal to act on a claim in restriction practice in fact amounts to a rejection in *In re Haas*, 179 U.S.P.Q. 623, 625 (C.C.P.A. 1973). As the foregoing excerpt from *Weber* explains, § 121 does not provide a basis for rejecting a particular claim. *See Weber* at 332. Accordingly, § 121 does not empower the P.T.O. to refuse to examine a single claim on the merits simply because the P.T.O. asserts that the claim is drawn to independent and distinct inventions. Rather, the "basic right of the applicant to claim his invention as he chooses" under § 112 is "paramount" over the P.T.O.'s right to control "such administrative matters as examiner caseloads and amount of searching done per filing fee." *See Weber* at 332.

Group I contains two independent claims, claims 1 and 3, each of which recites a method for determining whether an HIV-1 or an individual infected with HIV-1, respectively, has in increased likelihood of being hypersusceptible to protease inhibitors by detecting a mutation associated with such hypersusceptibility. Both of these independent claims are affected by the P.T.O.'s renewed Restriction Requirement.

Restriction of the subject matter of a single claim is improper for several reasons. To begin with, restriction within a single claim amounts to a rejection on the basis of 35 U.S.C. § 121 as specifically forbidden by *Weber* and *Haas*. These cases unambiguously and authoritatively hold that § 121 simply does not empower the P.T.O. to refuse to consider a

single claim on the grounds that it is drawn to independent and distinct inventions. Thus, refusal to consider each of claims 1 and 3 as filed constitutes an improper rejection on the basis of § 121 in direct contravention of the settled law.

Under the standard of *Weber*, Applicants have the right to have each claim examined on the merits. Restriction within, for example, claim 1 and concomitant dispersal of the claimed subject matter to separate claims ends the investigation of patentability of claim 1 before it begins. To be patentable, a claim must satisfy the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. As discussed above, there is no basis for rejecting a claim under § 121. *See Weber* at 332. If the subject matter of claim 1 is dispersed to multiple fragmentary claims, then it will never be determined whether claim 1 comports with §§ 101, 102, 103, and 112 and is otherwise patentable. Thus, restriction within a single claim denies Applicants their right to have each claim considered on the merits.

Restriction within any of these single claims to a single species, each reciting a particular protease inhibitor, also does not allow Applicants to claim their invention as they define it under 35 U.S.C. § 112. While restriction of a number of claims to different applications does not affect this right, restriction within a claim vitiates Applicants' prerogative to claim their invention as they choose. Applicants have defined their invention to be, for example, the subject matter recited by claim 1. If the Restriction Requirement is imposed and the subject matter of claim 1 is dispersed to many claims, the P.T.O. would define Applicants' invention, as unambiguously prohibited in *Weber*. Further, restriction within a single claim improperly limits the scope of Applicants' invention as claimed in view of their description of the invention. Applicants have described methods applicable to a genus of structurally related protease inhibitors. Under 35 U.S.C. § 112, Applicants are entitled to patent protection commensurate with their disclosure. Accordingly, restriction within a single claim is improper as it denies Applicants the right to claim their invention as they choose.

In addition, the totality of the resulting fragmentary claims following restriction within claim 1 would not necessarily be the equivalent of original claim 1 as cautioned by *Weber*. If claim 1 is internally restricted, Applicants would be forced to prosecute fragments of claim 1, each drawn to methods relating to a particular species of protease inhibitor in a number of applications. Even if Applicant pursued this course, the scope of coverage of the resulting fragmentary claims would not be likely to be equivalent to original claim 1. Thus, restriction within claim 1 improperly limits the scope of Applicants' invention methods

relating to individual species of protease inhibitor in view of Applicants' description of methods applicable to the entire genus of protease inhibitors.

Finally, restriction within a single claim places an undue burden on Applicants in achieving patent protection of the invention as currently claimed. If Applicants are restricted to individual species of particular protease inhibitors, Applicants would need to prosecute at least six different patent applications, each directed to an individual species, to obtain equivalent coverage. It is unreasonable for the P.T.O. to require Applicants to prosecute six additional applications when the P.T.O. has established procedures that minimize the burden on the P.T.O. in examining generic claims.

Applicants respectfully submit that the proper procedure for reducing the administrative burden on the P.T.O. when examining a generic claim is Election of Species. According to this practice, Applicants elect a species upon which the generic claims read in order to facilitate examination of such claims. Where both generic and specific claims are presented in an application, election of species to facilitate the examination of the generic claims is proper. *See* M.P.E.P. § 808.01(a). Even where no specific species claims are presented, election of species is proper when examination of the generic claims would require an unduly extensive or burdensome search. *See id.*

Accordingly, Applicants propose to elect a species encompassed by the generic claims to facilitate prosecution on the merits. *See id.* Should the P.T.O. conclude that an Election of Species is in fact proper, Applicants could, for example, elect the species of methods for determining whether an HIV-1 has an increased likelihood of being hypersusceptible to protease inhibitors in which the protease inhibitor is amprenavir, to facilitate prosecution on the merits.[1] Should Applicants elect this species, Applicants believe that claims 1-4, 6, 7, 18, and 19 would read upon the elected species.

Such an election of species would reduce the administrative burden on the P.T.O. while preserving Applicants' right to claim their invention as they choose. Therefore, Applicants respectfully request that the outstanding Restriction Requirement be withdrawn.

As shown by the foregoing discussion, the Restriction Requirement imposed by the P.T.O. communication of March 31, 2006, does not comport with 35 U.S.C. § 121,

[1] Applicants intend only to provide an example of a species which could be elected to facilitate prosecution of the instant application. Applicants reserve the right to elect this or another species should the P.T.O. substitute an Election of Species for the outstanding Restriction Requirement.

37 C.F.R. §1.141, and M.P.E.P. §§ 800 *et seq.* In accordance with the proper procedures, Applicants stand ready to elect a species to facilitate examination of the generic, subgeneric, and specific claims of the instant application. Accordingly, Applicants respectfully request reconsideration of the Restriction Requirement pursuant to 37 C.F.R. § 1.143.

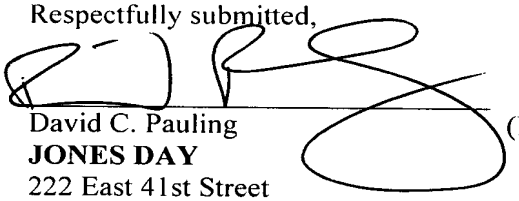
CONCLUSION

Applicants submit that claims 1-21 satisfy all of the criteria for patentability and are in condition for allowance. An early indication of the same is therefore kindly solicited.

No fee in addition to the Extension Fee is believe due in connection with this response. However, the Commissioner is authorized to charge any required fee to Jones Day Deposit Account No. 50-3013 (order no. 141333-999276).

Respectfully submitted,

Date: July 31, 2006



56,056
(Reg. No.)

David C. Pauling
JONES DAY
222 East 41st Street
New York, New York 10017
(212) 326-3939